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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,483	03/19/2001	Yoshinobu Hanyu	P20757	8955

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	17

DATE MAILED: 09/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,483	HANYU ET AL.	
	Examiner	Art Unit	
	Arun Chakrabarti	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Continued Examination Under 37 CAR 1.114

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on July 17, 2002 has been entered.

Specification

2. Claim 33 has been amended.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 34 and 35 are rejected under 35 U.S.C. 103 (a) over Bergstrand et al. (U.S. Patent 6,103,697) (August 15, 2000).

Bergstrand et al. teach a powder containing a physiologically active peptide, wherein the powder is made up of particles comprising a physiologically active peptide and mannitol (Column 12, lines 52-65), the particles further comprising nonionic surfactant lecithin (Column 13, lines 53-57) and a nonionic, organic, and a binder polyvinylpyrrolidone (Column 12, lines 56 to 65).

Bergstrand et al do not teach a powder comprising a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the non-ionic surfactant in an amount from 0.05 to 3 parts by weight and the water soluble binder in an amount of from 0.05 to 6 parts by weight.

However, it is *prima facie* obvious that selection of the specific ratio of weights of surfactant and binder represents routine optimization with regard to sequence, length and compositions of physiologically active peptide, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions

> of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the weight ratio selection of ingredients of the powder was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

5. Claims 33, 36-45, and 49-54 are rejected under 35 U.S.C. 103 (a) over Bergstrand et al. (U.S. Patent 6,103,697) (August 15, 2000) in view of Oyama et al. (U.S. Patent 6,117,434) (September 12, 2000).

Bergstrand et al. teach a powder containing a physiologically active peptide, wherein the powder is made up of particles comprising a physiologically active peptide and mannitol (Column 12, lines 52-65), the particles further comprising nonionic surfactant lecithin (Column 13, lines 53-57) and a nonionic, organic, and a binder polyvinylpyrrolidone (Column 12, lines 56 to 65).

Bergstrand et al. teach a powder containing a physiologically active peptide, for which drying of the aqueous liquid was performed by lyophilization (Example 34, Column 9, lines 58-60).

Bergstrand et al. teach a powder containing a physiologically active peptide, wherein the physiologically active peptide is human growth hormone (Column 2, lines 15-20).

Bergstrand et al. teach the composition, wherein the average size of the particles is 1-10 micrometer (Column 13, lines 41-43).

Bergstrand et al. teach an inhalant composition containing a physiologically active peptide (Column 12, lines 43-45, and Column 13, lines 38-41).

Bergstrand et al do not teach a powder comprising a physiologically active peptide and mannitol in a weight proportion of from 1:1 to 1:50, the non-ionic surfactant in an amount from 0.05 to 3 parts by weight and the water soluble binder in an amount of from 0.05 to 6 parts by weight.

However, it is *prima facie* obvious that selection of the specific ratio of weights of surfactant and binder represents routine optimization with regard to sequence, length and compositions of physiologically active peptide, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the weight ratio selection of ingredients of the powder was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Bergstrand et al do not teach the hydrogenated lecithin as one of the ingredients of the composition.

Oyama et al teach the hydrogenated lecithin as one of the ingredients of the composition (Column 2, lines 32 to Column 3, line 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the hydrogenated lecithin as one of the ingredients of the composition of Oyama et al into the powder composition of Bergstrand et al, since Bergstrand et al. state, "These type of drugs have an urgent need on the market, instead of or as a complement to present more toxic drugs, for the treatment of many diseases (Column 14, lines 50-52)." Oyama et al further provides motivation as Oyama et al state, "The lecithin is preferably hydrogenated lecithin in view of oxidation stability (Column 2, lines 32-33)". By employing scientific reasoning, an ordinary artisan would have combined and substituted the hydrogenated lecithin composition of Oyama et al. into the inhalant powder composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Bergstrand et al in order to improve the inhalant growth factor drug formulation. An ordinary practitioner would have been motivated to combine and substitute the hydrogenated lecithin composition of Oyama et al. into the inhalant powder composition containing a physiologically active peptide wherein the average size of the particles is 1-10 micrometer of Bergstrand et al in order to achieve the express advantages, as noted by Bergstrand et al., of drugs that have an urgent need on the market, instead of or as a complement to present more toxic

drugs, for the treatment of many diseases and also to achieve the express advantages, as noted by Oyama et al., of an invention that provides the use of lecithin which is preferably hydrogenated lecithin in view of oxidation stability.

6. Claims 46-48 are rejected under 35 U.S.C. 103 (a) over Bergstrand et al. (U.S. Patent 6,103,697) (August 15, 2000) in view of Oyama et al. (U.S. Patent 6,117,434) (September 12, 2000) further in view of Hughes et al. (U.S. patent 6,335,316 B1) (January 1, 2002).

Bergstrand et al. in view of Oyama et al teach the powder of claims 33, 36-45, and 49-54 as described above.

Bergstrand et al in view of Oyama et al do not teach the powder, wherein the physiologically active peptide comprises human insulin.

Hughes et al teach the powder, wherein the physiologically active peptide comprises human insulin (Abstract and Column 2, line 38 to column 3, line 16 and Examples 1 and 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the powder, wherein the physiologically active peptide comprises human insulin of Hughes et al into the powder composition of Bergstrand et al in view of Oyama et al, since Hughes et al. state, "Such administration can be effective for treating disorders such as diabetes or hyperglycemia (Column 7, lines 8-9)." Highes et al further provides motivation as Hughes et al state, "For example, delivery by such inhalation devices is advantageously reliable, reproducible, and accurate (Column 8, lines 55-56)". By employing scientific reasoning, an ordinary artisan would have combined and substituted the powder,

wherein the physiologically active peptide comprises human insulin of Hughes et al into the powder composition of Bergstrand et al in view of Oyama et al in order to improve the inhalant growth factor drug formulation. An ordinary practitioner would have been motivated to combine and substitute the powder, wherein the physiologically active peptide comprises human insulin of Hughes et al into the powder composition of Bergstrand et al in view of Oyama et al in order to achieve the express advantages, as noted by Hughes et al., of such administration that can be effective for treating disorders such as diabetes or hyperglycemia and which is advantageously reliable, reproducible, and accurate.

Response to Amendment

7. In response to amendments, all previous 103 (a) rejections are hereby withdrawn. However, three new 103 (a) rejections have been included.

Response to Arguments

8. Applicant's arguments with respect to new claims 33-54 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this

Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

July 22, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600